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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,403	12/22/2003	Wolfgang Guba	21553	8964

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HOFFMANN-LA ROCHE INC.  
PATENT LAW DEPARTMENT  
340 KINGSLAND STREET  
NUTLEY, NJ 07110

EXAMINER

STOCKTON, LAURA

ART UNIT PAPER NUMBER

1626

DATE MAILED: 10/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/743,403

**Applicant(s)**

GUBA ET AL.

**Examiner**

Laura L. Stockton, Ph.D.

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 May 2005.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.  
4a) Of the above claim(s) 32 and 35-39 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-5, 7-12, 15, 17-21, 23-31, 33 and 34 is/are rejected.  
7) ☒ Claim(s) 6, 13, 14, 16 and 22 is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_

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**DETAILED ACTION**

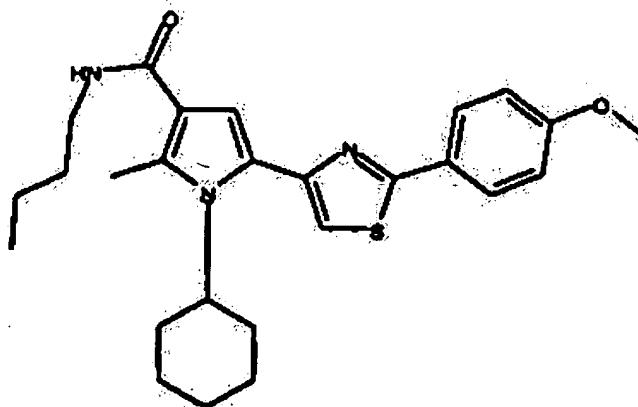
Claims 1-39 are pending in the application.

***Election/Restrictions***

Applicants' election with traverse of Group I, and the species of Example 8 found on pages 36-37 of the instant specification (reproduced below), in the reply filed on January 10, 2005 was acknowledged in the previous Office Action. The requirement was deemed proper and therefore made FINAL in the previous Office Action.

**Example 8**

Cyclohexylmethyl-5-[2-(4-methoxy-phenyl)-thiazol-4-yl]-2-methyl-1H-pyrrole-3-carboxylic acid butylamide



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Claims 32 and 35-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions. Applicant timely traversed the restriction (election) requirement in the reply filed on January 10, 2005.

Rejections made in the previous Office Action that do not appear below have been overcome by Applicants' amendments to the claims. Therefore, arguments pertaining to these rejections will not be addressed.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

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*Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 7-12, 15, 17-21, 23-31, 33 and 34 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10, 16 and 33 of copending Application No. 10/743,642 {US 2004/016712}. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claimed compounds are generically described in the copending application.

The indiscriminate selection of "some" among "many" is *prima facie* obvious, *In re Lemin*, 141 USPQ 814 (1964). The motivation to make the claimed compounds

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derives from the expectation that structurally similar compounds would possess similar activity (e.g., treating anxiety).

One skilled in the art would thus be motivated to prepare products embraced by the copending application to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful in treating, for example, anxiety. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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***Response to Arguments***

Applicants' arguments filed May 31, 2005 have been fully considered. Applicants request that this rejection be held in abeyance until all other issues have been overcome.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 12, 23, 24, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sanfilippo et al. {U.S. Pat. 5,342,851}.

***Determination of the scope and content of the prior art (MPEP***

***§2141.01)***

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Applicants claim pyrrolyl-thiazole compounds. Sanfilippo et al. teach pyrrolyl-thiazole compounds that are structurally similar to the instant claimed compounds. See in Sanfilippo et al. (columns 2-3; and column 4, lines 13-21), for example, formula III wherein R is hydrogen; R<sub>3</sub> is hydrogen; A is carboxamido; B is alkyl; and Q is alkoxy; or Example 233 in column 34.

*Ascertainment of the difference between the prior art and the claims*

*(MPEP §2141.02)*

The difference between the compounds of the prior art and the compounds instantly claimed is that of positional isomerism.

*Finding of prima facie obviousness--rational and motivation (MPEP*

*§2142-2413)*

Nothing unobvious is seen in substituting the known claimed isomer for the structurally similar isomer, as taught by Sanfilippo et al., since such structurally



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related compounds suggest one another and would be expected to share common properties (e.g., treating reperfusion thrombosis) absent a showing of unexpected results. In re Norris, 84 USPQ 458 (1950).

One skilled in the art would thus be motivated to prepare positional isomers of the compounds taught in the prior art to arrive at the instant claimed products with the expectation of obtaining additional beneficial products that would be useful in treating reperfusion thrombosis. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

### ***Response to Arguments***

Applicants' arguments filed May 31, 2005 have been fully considered. Applicants argue that: (1) a *prima facie* case of obviousness has not been established; (2) there is no motivation to modify the compounds of

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Sanfilippo et al.; (3) the majority of specie exemplified by Sanfilippo et al. are either pyrazole-thiazole compounds or phenyl-thiazole compounds and not the instant claimed pyrrolyl-thiazole compounds; (4) the pyrrolyl-thiazole specie exemplified by Sanfilippo et al. are structurally different because the compounds have different substitution patterns from the compounds instantly claimed; (5) since the generic structures and specie in Sanfilippo et al. are extremely broad and/or different from the present claimed invention, there is no motivation to modify Sanfilippo et al. to obtain the compounds of the present invention; and (6) Sanfilippo et al. teach a different utility than that which is disclosed for the instant claimed compounds.

All of Applicants' arguments have been considered but have not been found persuasive. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for

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establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**1. Determining the scope and contents of the prior art.**

Applicants claim pyrrolyl-thiazole compounds.

Sanfilippo et al. teach pyrrolyl-thiazole compounds that are structurally similar to the instant claimed compounds.

**2. Ascertaining the differences between the prior art and the claims at issue.**

The difference between the compounds of the prior art and the compounds instantly claimed is that of positional isomerism.

**3. Resolving the level of ordinary skill in the pertinent art.**

Nothing unobvious is seen in substituting the known claimed isomer for the structurally similar isomer, as

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taught by Sanfilippo et al., since such structurally related compounds suggest one another and would be expected to share common properties.

**4. Considering objective evidence present in the application indicating obviousness or nonobviousness.**

One skilled in the art would thus be motivated to prepare positional isomers of the compounds taught in the prior art to arrive at the instant claimed products with the expectation of obtaining additional beneficial products that would be useful in treating reperfusion thrombosis.

Each of the factual inquiries have been addressed and there is sufficient motivation from Sanfilippo et al. to prepare the instant claimed compounds.

Additionally, Applicants' genus has a number of variables and their permutations and combinations result in a vast number of compounds which are generically claimed. It is not agreed that the teaching in Sanfilippo et al. is extremely broad and would not direct one skilled in the art toward the

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instant claimed compounds. Sanfilippo et al. clearly teach that the compounds of formula (III) are of interest.

Applicants argue that the majority of specie exemplified by Sanfilippo et al. are either pyrazole-thiazole compounds or phenyl-thiazole compounds and not the instant claimed pyrrolyl-thiazole compounds and those pyrrolyl-thiazole compounds prepared are structurally different than the instant claimed compounds.

In response, it is well established that consideration of a reference is not limited to the preferred embodiments or working examples, but extends to the entire disclose for what it fairly teaches, when viewed in light of the admitted knowledge in the art, to person of ordinary skill in the art. In re Boe, 148 USPQ 507, 510 (CCPA 1966). Further, it would appear that Applicants are arguing that if a rejection under 35 USC § 102 cannot be made than a rejection under 35

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USC § 103 should not be made. However, this is not the basis for determining obviousness.

Applicants argue that Sanfilippo et al. teach a different utility than that which is disclosed for the instant claimed compounds. In response, there is no requirement that the prior art must suggest that the claimed product will have the same or similar utility as that discovered by applicant in order to support a legal conclusion of obviousness. In re Dillon, 16 U.S.P.Q. 2d 1897, 1904 (Fed. Cir. 1990). Further on page 24 in paragraph [0071], Applicants disclose that the instant compounds are useful in treating, for example, cardiovascular disorders and inflammations. Sanfilippo et al. teach that their compounds are also useful in treating cardiac infarct and inflammation (column 4, lines 13-21). Therefore, Sanfilippo et al. do teach Applicants' utility. For all the reasons given above, the instant claimed invention would have been obvious to one skilled in the art.

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The elected species of Example 8 is not allowable because of the claimed subject matter of copending application 10/743,642.

### ***Allowable Subject Matter***

Claims 6, 13, 14, 16 and 22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Conclusion***

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

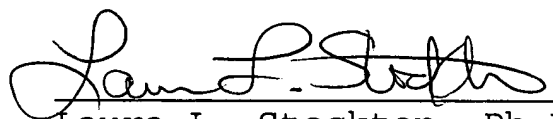
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

A handwritten signature in black ink, appearing to read "Laura L. Stockton", written over a horizontal line.

Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

October 6, 2005